IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

UNITED STATES OF AMERICA ex rel. THE ESTATE OF JOHN DONEGAN,	)	
Plaintiff and Relator,	)	
v.	)	No. 4:12-CV-0876-DGK
ANESTHESIA ASSOCIATES OF KANSAS CITY, PC,	)	
Defendant.	)	

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND DENYING RELATOR'S MOTION FOR PARTIAL SUMMARY JUDGMENT

This is a *qui tam* action in which the Estate of John Donegan ("Relator"),[1] alleges Defendant Anesthesia Associates of Kansas City, P.C. ("Defendant" or "AAKC"), violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, by submitting false claims to Medicare and Medicaid for reimbursement of anesthesiology services. Relator contends Defendant's anesthesiologists violated the "Seven Steps" regulation setting the conditions of payment for Medically Directed anesthesia services by failing to personally participate in a patient's emergence from anesthesia in the operating room.

Now before the Court are the parties' cross-motions for summary judgment (Docs. 236 and 242) and Defendant's motion to strike Relator's motion for summary judgment for failure to comply with Rule 56 and Local Rule 56.1 (Doc. 255). In ruling on these motions, the Court has considered a small mountain of briefing submitted by the parties, including Documents 237, 243, 256-57, 259, 274, 276-77, and 279, as well as all of the parties' previous filings, including

[1] John Donegan filed this action and passed away while the litigation was pending. Pursuant to Fed. R. Civ. P. 25(a), the Court substituted his estate as Relator. Order Granting in Part Motion to Substitute (Doc. 303). Because the Relator is now an estate, a genderless legal entity, the Court uses the pronoun "it" to refer to Relator.

Documents 144, 156, 167, 171, and 174. The Court has also carefully read the "Statement of Interest" (Doc. 272) filed by the United States concerning the scienter required for an FCA violation.

With respect to the motion to strike, the Court finds many of Defendant's objections to Relator's motion for summary judgment are well-made. Much of Relator's briefing in support of its motion does not comply with Federal Rule of Civil Procedure 56. Instead of striking Relator's motion in its entirety, however, the Court will not consider Relator's proposed facts which violate Federal Rule of Civil Procedure 56(c) and 56(e).

With respect to the summary judgment motions, the Court holds Relator cannot establish that Defendant knowingly submitted a false claim. A relator "must show that there is no reasonable interpretation of the law that would make the allegedly false statement true." *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1191 (8th Cir. 2010). The Court finds the meaning of "emergence" as used in the regulation is ambiguous, and Defendant's interpretation of the regulation is reasonable. Hence, Defendant is entitled to summary judgment and Relator is not entitled to partial summary judgment.

Accordingly, the Court GRANTS IN PART Defendant's motion to strike (Doc. 255); GRANTS Defendant's motion for summary judgment (Doc. 242); and DENIES Relator's motion for partial summary judgment (Doc. 236).

Summary Judgment Standard

A moving party is entitled to summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The movant bears the initial responsibility of informing the court of the basis for its motion, and it must identify those portions of the record which demonstrate the

absence of a genuine issue of material fact. *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir. 2011). If the movant does so, then the nonmovant must respond by submitting evidence demonstrating that there is a genuine issue for trial. *Id.* The court views any factual disputes in the light most favorable to the nonmoving party. *Id.* Decisions concerning credibility determinations, how to weigh the evidence, and what inferences to draw from the evidence, are decisions reserved for the jury, not the judge. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Nor can the moving party "create sham issues of fact in an effort to defeat summary judgment." *RSBI Aerospace, Inc. v. Affiliated FM Ins. Co.*, 49 F.3d 399, 402 (8th Cir. 1995) (citation omitted). The nonmoving party must set forth specific facts showing there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Each fact must be set forth in a separately numbered paragraph. L.R. 56.1(a). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." *Ricci v. DeStefano*, 557 U.S 557, 585 (2009).

Background of Applicable Regulations

Relator alleges that Defendant AAKC violated the FCA by knowingly submitting false claims for anesthesiology services to the agency which administers Medicare and Medicaid, the Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration, which is part of the Department of Health and Human Services

("HHS"). To understand the issues in this lawsuit, some explanation of the regulations governing reimbursement for anesthesia services is necessary.

CMS pays anesthesiology providers at different rates, depending on how involved the anesthesiologist was in the procedure. CMS has designated four levels of reimbursement for anesthesiology services: (1) Personally Performed, (2) Medical Direction, (3) Medical Supervision, and (4) Not-Medically Directed. The first two are particularly relevant to this case. The requirements for billing at each level are as follows.

i. Personally Performed.

Generally speaking, an anesthesiology service is Personally Performed when the anesthesiologist performs "the entire anesthesia service alone." 42 C.F.R. § 414.46(c)(1). For such service, the anesthesiologist is paid at a rate determined by a formula. *Id.* § 414.46(c)(2).

ii. Medical Direction.

Anesthesiology service is paid at the Medical Direction rate when the anesthesiologist is directing Certified Registered Nurse Anesthetists ("CRNAs") in two to four cases concurrently[2] and the anesthesiologist satisfies all conditions of the so-called "Seven Steps" regulation. *Id.* §§ 414.46(d), 415.110(a)(1). These conditions are that for each patient the anesthesiologist: (i) performs a pre-anesthetic examination and evaluation; (ii) prescribes the anesthesia plan; (iii) personally participates in the most demanding aspects of the anesthesia plan including, if applicable,[3] induction and *emergence*; (iv) ensures that any procedures in the anesthesia plan that the anesthesiologist does not perform are performed by a qualified individual as defined in operating instructions; (v) monitors the course of anesthesia administration at frequent intervals;

[2] Concurrent cases are those that overlap in time.

[3] The "if applicable" language of subsection three limits the emergence requirement to general anesthesia only. *See* 63 Fed. Reg. 58814-01, 58843 (Nov. 2, 1998).

(vi) remains physically present and available for immediate diagnosis and treatment of emergencies; and (vii) provides indicated post-anesthesia care. *Id.* § 415.110(a)(1). If one or more of these conditions are not met, the procedure should be billed as Medical Supervision. The Regulation does not define what "emergence" means, or when emergence begins or ends.

As for how the provider documents compliance with these steps, subsection (b) of the regulation states:

> The physician alone inclusively documents *in the patient's medical record* that the [seven] conditions set forth in paragraph (a)(1) of this section have been satisfied, specifically documenting that he or she performed the pre-anesthetic exam and evaluation, provided the indicated post-anesthsia care, and was present during the most demanding procedures, including induction and emergence where applicable.

Id. § 415.110(b) (emphasis added).

CMS has provided limited guidance interpreting this regulation. The predecessor to CMS published the final rule setting out the conditions for payment of Medical Direction for anesthesia services in 1998. *Id.* § 415.110(b). In one of the comments accompanying the final regulation, the agency addressed an inquiry it received from the American Society of Anesthesiologists ("ASA"). The ASA had asked whether its interpretation of the documentation requirement was correct. The ASA's position was that the requirement was met if the anesthesiologist states in the medical record that the Medical Direction standards have been met generally, but without addressing each individual standard. The anesthesiologist would, however, identify in the record those demanding aspects of the case in which he or she personally participated. 63 Fed. Reg. 58844.

The agency responded:

> We understand the ASA's concerns about the Medical Direction requirements. We do not wish to make the act of medical documentation overly burdensome to the anesthesiologist. However, the medical record must include an amount of documentation to enable a medical records' auditor to conclude that the physician was sufficiently involved to support the payment of a medical direction fee.
>
> . . . We do not believe it is onerous to require the medically directing physician to document that he or she performed the pre-anesthetic exam and evaluation, provided indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where indicated. We also expect that there would be some indication in the record that the medically directing physician was present during some portion of the anesthesia monitoring.

Id.

For each Medical Direction service, CMS pays the anesthesiologist 50 percent of the amount that he or she would have earned had he or she Personally Performed the service. *Id.* § 414.46(d)(3)(v). The remaining 50 percent is reimbursed to the CRNA or the group practice employing the CRNA. *Id.* §§ 414.46(d)(3), 414.60(a)(1). Thus, a practice with an anesthesiologist directing four cases concurrently can bill CMS for twice the total amount of an anesthesiologist performing four single procedures at the Personally Performed rate.[4] The practice can bill the remaining 50 percent for each of the four CRNAs the anesthesiologist directed. If each procedure takes the same amount of time whether performed by an anesthesiologist alone or a CRNA working under an anesthesiologist's supervision, a single anesthesiologist and four CRNAs billing at the Medical Direction rate could generate the same amount of revenue as one anesthesiologist performing four procedures at the Personally

[4] Four cases billed at 50 percent of the rate for a Personally Performed procedure generates the same amount of revenue as two Personally Performed procedures billed at 100 percent of the Personally Performed rate.

Performed rate. However, the anesthesiologist/four CRNAs model of practice could generate this revenue in one quarter of the time. Thus, billing at the Medical Direction rate is potentially a more efficient and more profitable practice model.

iii. Medical Supervision.

Anesthesiology service is reimbursed at the Medical Supervision rate when an anesthesiologist: (1) directs more than four cases concurrently, or (2) directs two to four cases but fails to comply with one or more of the seven conditions. The reimbursement rate is lower for Medical Supervision than for Medical Direction.

iv. Not-Medically Directed.

When a CRNA furnishes an anesthesia service that is not directed by an anesthesiologist, the procedure is billed as Not-Medically Directed.

Facts

At the outset, the Court declines to consider several of Relator's proposed facts in its briefing in support of its summary judgment motion. Several of Relator's proposed facts make multiple factual assertions that are intertwined with argument or legal conclusions. *See* L.R. 56.1(a) ("*Each fact* shall be set forth in a *separately numbered paragraph*." (emphasis added)). Where possible the Court has separated the factual assertion from the argument or legal conclusion and considered the merits of the proposed fact. Where it was not possible to separate them, the Court did not include the proposed fact. Further, several of Relator's proposed facts cite inadmissible evidence or material which is not part of the record, so the Court did not consider these proposed facts either. *See* Fed. R. Civ. P. 56(c), 56(e).

Similarly, the Court rejects several facts proposed in Relator's briefing in opposition to Defendant's motion for summary judgment. Suggestions in opposition to a motion for summary judgment must

> begin with a section that contains a concise listing of material facts as to which the party contends a genuine issue exists. Each fact in dispute shall be set forth in a separate paragraph, shall refer specifically to those portions of the record upon which the opposing party relies, and . . . shall state the paragraph number in movant's listing of facts that is disputed.

L.R. 56.1. Relator does not respond to Defendant's proposed facts individually as either "controverted" or "uncontroverted," and then, in a separate section, set forth additional uncontroverted facts relevant to Defendant's motion. Instead, Relator combines its responses to everything in two "Counterstatements" and "Additional Rebuttal" that randomly address Defendant's proposed uncontroverted material facts and interject proposed additional facts for the Court's consideration. To make matters more confusing, many of these responses and proposed additional facts are irrelevant, argumentative, conclusory, or not based on admissible evidence in the record.

Once again, the Court has tried to ignore the inadmissible portions of such responses and fairly consider the rest. Where this was not possible, pursuant to Federal Rule of Civil Procedure 56(c) and 56(e), the Court did not include Relator's proposed fact or treated Defendant's proposed fact as undisputed.

Finally, the Court has omitted as irrelevant all proposed facts relating to a fourth theory of liability Relator advanced at the summary judgment stage, namely that Defendant's anesthesiologists violated step three by failing to personally participate *in the most demanding*

aspects of emergence by not being present at extubation.[5] The Court recognizes that during discovery Realtor uncovered significant evidence supporting such a claim: facts indicating the importance of having an anesthesiologist present during extubation, that extubation is a vital aspect of emergence, and that Defendant's anesthesiologists were almost never present during extubation. As discussed below, the Court may not consider this theory since it was not pled in the Amended Complaint. Since the Court may not consider this theory, all facts supporting it are irrelevant and excluded.

With this in mind, for purposes of resolving the pending cross summary judgment motions, the Court finds the relevant, undisputed facts to be as follows.

Defendant AAKC is an anesthesia group practice that employs both anesthesiologists and CRNAs. At Menorah Medical Center ("MMC"), Defendant practices in a "Medical Direction Care Team Model" in which it bills Government health care providers at the Medical Direction rate 97.4 percent of the time.

Defendant typically performs anesthesia services at MMC in eight Operating Rooms ("OR"), two procedure rooms, and a gastrointestinal lab. Defendant staffs at least three anesthesiologists at any time depending on the number of operating/procedure rooms that will be utilized during the day for anesthesia services. A CRNA is typically assigned to each patient and remains in the OR with the patient throughout the procedure. An assigned anesthesiologist rotates between up to four rooms and the recovery room.

When an operation is completed, the CRNA typically transfers the patient to the recovery room. At MMC a patient is delivered to the recovery room by the CRNA generally within ten to twenty minutes after the operation ends. Once the patient is transferred to the recovery room, the

[5] "Extubation" is the removal of a tube from a patient's body. *PDR Medical Dictionary* 615-16 (1st ed. 1995). In this case, that means the removal of an endotracheal tube from a patient's airway.

CRNA's role in the care of the patient ends, and a recovery room nurse and an anesthesiologist continue to monitor the patient's care.

The recovery is designed to observe patients that are recovering from anesthesia. Nearly all patients receive supplemental oxygen in the recovery room to assist their recovery during emergence from anesthesia. The anesthesiologist determines when patients are recovered from anesthesia such that it is appropriate for them to be discharged or moved to a hospital room.

This case centers on the emergence period following anesthesia. CMS has not defined "emergence." There is also no National Coverage Determination defining "emergence."[6] AAKC's regional carrier through which it bills medicare claims, Wisconsin Physician Services ("WPS"), has not provided any guidance defining "emergence." The ASA has also not defined "emergence." There is no guidance from any national or state anesthesiology organization defining "emergence" because emergence is a process, and each patient is different. Some patients take longer than others to recover from the effects of anesthesia, and there are different levels of emergence. The University of Kansas Hospital, where some of AAKC's anesthesiologists and CRNAs received their education and training, teaches its anesthesiology residents and nurse anesthetist students that emergence occurs over a period of time and may take an hour or more.

Defendant defines "emergence" to include the patient's recovery in the recovery room. Defendant contends it was defined this way because the Professional Practice committee members agreed that emergence extends into the recovery room. Defendant's anesthesiologists

[6] The Secretary of HHS may issue a National Coverage Determination ("NCD") to provide guidance concerning what services are reimbursable. *United States ex. rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 19190096, at *1 (E.D.N.Y. May 13, 2014). HHS contracts with regional insurance carriers, in this case Wisconsin Physician Services, to provide payment services. *Id.* In the absence of an NCD, a regional carrier may create a guideline known as a Local Coverage Determination ("LCD"). *Id.* An LCD applies only to the issuing contractor's region. *Id.* at *4. An LCD issued in one region is not binding on a contractor in a different region. *Id.*

attempt to comply with the emergence requirement for each patient either by visiting the patient during the patient's emergence in the operating room, in the hallway during the patient's transfer to the recovery room, or after the patient arrives in the recovery room.

Relator, on the other hand, views emergence as excluding time in the recovery room. Relator's experts, two board certified anesthesiologists, disagree with the proposition that an anesthesiologist is present at "emergence" if he examines the patient in the recovery room. Dr. Brian McAlary opined, "Evaluating the patient in the [recovery room] is laudable, but does not comport with common usage of 'emergence.'" Expert Report of Brian McAlary, M.D., CHCQM (Doc. 259-18) at 6. Relator's other expert, Dr. Steve Yun, opined:

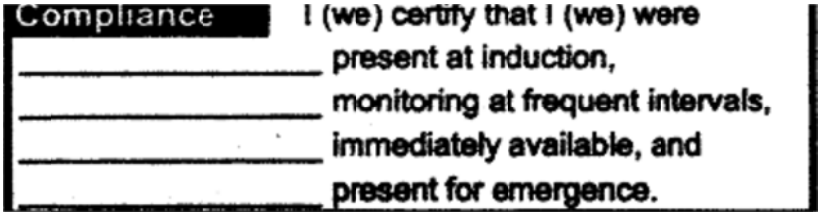
> It defies the widespread practice and common sense to argue that an anesthesiologist need NOT be present during . . . emergence in the operation room. This is in direct contrast to the intent and letter of the law, and the general understanding of the law in the anesthesiology community, as it pertains to Medical Direction.

Expert Report of Steve C. Yun, M.D. (Doc. 259-19) at 6. Dr. Yun also noted that Palmetto GBA, a nationwide Medicare carrier for railroad retirees to which Defendant submits some claims, defines "emergence" as "the period beginning with the cessation of delivery of anesthetic agents and ending at the time the patient is turned over to the staff of the recovery room or other qualified personnel." *Id.* Dr. Yun states this definition is consistent with his understanding of the term and is also widely embraced by the anesthesiology community.

CRNA John Donegan testified that Defendant's anesthesiologists are almost never present in the operating room for emergence. Defendant's Chair of Anesthesia at MMC testified that 70 percent of the time she certifies that she was present for emergence, she does not actually see the patient until after the patient has left the operating room. Other defense witnesses,

including one of Defendant's anesthesiologists, acknowledged that Defendant's anesthesiologists oftentimes do not return to the operating room for emergence.

Defendant documents the anesthesia services it renders in several records. The form relevant to the sole remaining claim in this case is the Anesthesia Services Record.[7] It contains a "Compliance" box in which the anesthesiologist may initial up to four lines certifying certain things. This box is as follows:


Compliance I (we) certify that I (we) were
_____ present at induction,
_____ monitoring at frequent intervals,
_____ immediately available, and
_____ present for emergence.

Defendant submits claims for Medical Direction reimbursement based solely on whether these four lines are completed. If the anesthesiologist initials each line, a claim is submitted for Medical Direction reimbursement. It is unclear what happens when all four lines are not initialed.

The Anesthesia Services Record is a carbon-copy form. The top copy is removed when the patient leaves the operating room and is sent to Defendant's billing office. The bottom copy stays with the patient's file which is held by MMC. An anesthesiologist may make an additional notation to the bottom copy after it is separated from the top. Any notation made after the two are separated would not be shown on the top copy. To determine the extent to which an anesthesiologist has documented compliance, each patient's individual medical record—which is held by MMC—must be reviewed.

During discovery, Defendant produced its patient files for approximately 13,000 Medical Direction claims submitted to the government for services provided at MMC from July 10, 2006,

[7] Defendant's proposed statement of fact reads "Anesthesia Services Form," but it appears Defendant meant to write "Anesthesia Services Record" since they appear to be the same thing.

through December 31, 2013. For 724 of these claims, one of the lines in the top copy of the Anesthesia Services Record maintained by Defendant is not signed. Relator submitted 50 of these patient files held by Defendant to the Court as representative examples. Only 19 of the complete patient files held by MMC are part of the record, and the bottom copy of the Anesthesia Services Record in these files show the anesthesiologist did, in fact, completely fill out the Anesthesia Services Record.

Discussion

I. Defendant is entitled to summary judgment on Counts I and II because Relator cannot establish that Defendant knowingly submitted any false claims.

Relator pled three theories of liability in the Amended Complaint. Relator has abandoned its second and third theories.[8] Suggestions in Opp'n to Def.'s Mot. for Summ. J. (Doc. 259) at 29 n.84. Relator's first and sole remaining theory is that Defendant's anesthesiologists violated step three of the Seven Steps regulation by virtually never personally participating in the emergence of a patient coming out of a general anesthetic in the operating room. Am. Compl. at ¶ 60; *see also* ¶¶ 61-62,[9] 76, 97-99, 107-08, 116, 132, 139. This claim is grounded in Relator's contention that emergence does not extend into the recovery room.

Relator has attempted to assert a fourth theory of FCA liability: that Defendant's anesthesiologists violated step three of the regulation by failing to "personally participate *in the*

[8] The abandoned theories are that Defendant's anesthesiologists violated step two by routinely failing to prescribe the anesthetic agents to be administered, Am. Compl. at ¶ 71; and that Defendant's anesthesiologists occasionally violated step five by failing to monitor patients at "frequent" intervals. *Id.* at ¶ 72.

[9] The Court recognizes that paragraph 61 of the Amended Complaint also states that "consistent with their actual services rendered" Defendant's anesthesiologists "routinely initialed the first three boxes, but routinely did not initial" the present for emergence box, yet still billed for Medical Direction. Am. Compl. at ¶ 61. It is unclear if Relator is arguing that such a practice violates the FCA. Even if Relator were, the record developed during discovery conclusively demonstrates Defendant did not routinely initial the first three boxes and leave the fourth blank. Of the 13,000 procedures Defendant billed at the Medical Direction rate, the anesthesiologist initialed the present for emergence box in 12,276 of these procedures. Hence, there is no merit to this claim.

most demanding aspects of the anesthesia plan including . . . emergence" if they were not present for extubation. Suggestions in Opp'n to Def.'s Mot. for Summ. J. at 36-37, 37 n.97 (emphasis added).

A. The Court will not consider Relator's fourth theory of liability.

Although this fourth theory may well be meritorious, Relator may not assert it now because it was not asserted in the Amended Complaint.[10] A relator may not assert new theories of liability based on information learned during discovery. *See United States ex. rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 558-60 (8th Cir. 2006) (approving the district court's refusal to grant the relator leave to amend or relax Rule 9(b) requirements to allow the relator to plead his complaint generally and amend it with specifics after discovery). Like other fraud claims, qui tam claims are subject to Rule 9(b)'s heightened pleading requirements. *Drobnak v. Andersen Corp.*, 561 F.3d 778, 783 (8th Cir. 2009). The relator "must plead the who, what, where, when, and how of the alleged fraud." *Id.* Where the relator claims systemic fraud in violation of the FCA, the relator need not "allege specific details of *every* alleged fraud claim," but "must provide some representative examples of [the] alleged fraudulent conduct, specifying the time, place, and content of [the] acts and the identity of the actors." *Joshi*, 441 F.3d at 557 (emphasis in original). A relator cannot plead an FCA violation generally and then "'fill in the blanks' following discovery." *Id.* at 559. As the *Joshi* court cautioned, permitting a relator to assert new theories of liability after conducting discovery would enable the relator to conduct an end-run around the heightened pleading standard, effectively allowing the relator to file a flimsy lawsuit

[10] Relator's assertion that it was pled in paragraphs 60 through 63 of the Amended Complaint, Suggestions in Opp'n to Def.'s Mot. for Summ. J. at 37 n.97, is false. These four paragraphs allege Defendant's anesthesiologists were not present for emergence. These paragraphs do not claim that the anesthesiologists were not present for the most demanding aspects of the anesthesia plan. In fact, these paragraphs do not even contain the words "most demanding aspects of the anesthesia plan," a term of art under step three. This phrase is used only three times in the entire Amended Complaint: once when quoting the Seven Steps regulation, and twice in passing in discussing the placement of a spinal anesthetic in a patient. Am. Compl. at ¶¶ 55, 120, 123.

subjecting the defendant to time-consuming and expensive discovery in the hope of uncovering an unknown wrong or extracting a settlement from the defendant. *Id*. at 559. Because Relator's fourth theory describes a distinct, independent scheme of how Relator allegedly defrauded the Government, it should have been pled in the Amended Complaint or at least provided as a representative example of fraudulent conduct. It was not, and so the Court cannot consider this theory of liability.

B. Relator cannot establish Defendant "knowingly" made false claims.

The Court now turns to whether Defendant is entitled to summary judgment on the two counts left in this case, which concern the same theory of liability. Count I alleges Defendant violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented a false claim for payment to the Government when it caused Medical Direction claims to be submitted to the Government which Defendant knew did not meet the conditions for such claims. Am. Compl. at ¶¶ 144-46. Count II alleges Defendant violated 31 U.S.C. § 3729(a)(1)(B) by knowingly making or causing to be made a false *record* material to a false claim when its anesthesiologists routinely directed that all anesthesia treatments should be billed as Medically Directed. To establish FCA liability under either count, Relator must show: (1) the defendant made a claim against the United States; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent. *United States ex rel. Raynor v. Nat'l Rural Utils. Co-op Fin., Corp.*, 690 F.3d 951, 955 (8th Cir. 2012).

Relator's remaining theory of liability is that Defendant made false claims by billing at the Medical Direction rate even though its anesthesiologists violated step three of the "Seven Steps" regulation by "virtually never 'personally participat[ing]' in the 'emergence' of a patient coming out of a general anesthetic" in the operating room. Am. Compl. at ¶ 60; *see also* ¶¶ 61-

62,76, 97-99, 107-08, 116, 132, 139. This claim rests on Relator's assertion that emergence ends as the patient is wheeled into the recovery room.

Defendant argues Relator cannot prove the second element of an FCA violation, that it *knowingly* submitted false claims. Defendant contends the regulation is ambiguous as to what constitutes emergence; that its interpretation that emergence extends into the recovery room is reasonable; and that the Eighth Circuit has held recently that a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013). As a result, there can be no liability.

In response, Relator points out that the FCA requires it to show only that Defendant submitted a false claim with "reckless disregard" or "deliberate indifference." Relator argues that reimbursement regulations do not have to be drafted with impossible specificity or mathematical precision, and that Defendant is using a gratuitous and extremely broad definition of "emergence" as a de facto substitute for the third Medical Direction step. Relator contends "emergence" should be interpreted according to its common meaning in the medical community, and that it has placed evidence in the record demonstrating that the Government and the medical community understand that being present for emergence means being present in the operating room as the patient is weaned from anesthesia. Relator suggests that even if the regulation is ambiguous, it need only show that Defendant knew that CMS interpreted the regulation in a certain way and its actions did not comply with this interpretation.

1. *Ketroser* and *Hixson* provide the applicable guidance as to the scienter necessary to establish an FCA violation.

The FCA prohibits "knowingly" presenting a false claim for government payment, but not negligently presenting a false claim. 31 U.S.C. § 3729(a); *Minn. Ass'n of Nurse Anesthetists*

v. Allina Health, 276 F.3d 1032, 1053 (2002). A defendant acts "knowingly" under the FCA not only when he or she "has actual knowledge of the information," but also when he or she "acts in deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. 31 U.S.C. § 3729(b).

Although exactly what constitutes "deliberate ignorance" or "reckless disregard" is somewhat uncertain, the Eighth Circuit has made clear what does *not* constitute "deliberate ignorance" or "reckless disregard." The Eighth Circuit recently held in *United States ex rel. Ketroser v. Mayo Foundation* that where a regulation is unclear, a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." 729 F.3d 825, 832 (8th Cir. 2013). This is consistent with its 2010 decision in *United States ex rel. Hixson v. Health Management Systems, Inc.* that a bill submitted "based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute." 613 F.3d at1190. To prevail in an FCA action the relator "must show that there is no reasonable interpretation of the law that would make the allegedly false statement true." *Id.* at 1191. This is true even if the defendant's behavior is somewhat opportunistic. "[A] defendant does not act with the requisite deliberate ignorance or reckless disregard by 'taking advantage of a disputed legal question.'" *Id.* (quoting *Hagood v. Sonoma Cnty. Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996)).

In its Statement of Interest, the United States urges the Court to read *Hixson* differently and apply a different standard, one that looks beyond whether a defendant's interpretation was reasonable and considers other evidence to determine whether the defendant acted knowingly. It suggests that to be consistent with the holding in *Allina, Hixson* must be interpreted as standing for "the unremarkable proposition that a defendant who submits a false claim with a good faith

belief that its claim is true, based on its real time understanding of a governing regulation, lacks the requisite knowledge to be found liable for an FCA violation." Statement of Interest (Doc. 272) at 5. The United States contends that "what steps the defendant took to ascertain the government's construction of an ambiguous regulation is also relevant to evaluating whether the defendant acted with knowledge." *Id.* at 6. "Contractors doing business with the government are expected to take reasonable steps to verify that their interpretation of a regulation is correct before submitting claims for payment." *Id.* For support, the United States cites the FCA's legislative history and two cases, *Heckler v. Community Health Services*, 467 U.S. 51, 64 (1984) (reasoning that a participant in a Medicare program "had a duty to familiarize itself with the legal requirements for cost reimbursement"), and *Anesthesiologists Affiliated v. Sullivan*, 941 F.2d 678, 681 (8th Cir. 1991) (finding the defendant was indifferent to the accuracy of its billing claims, and holding it had an obligation to determine whether it was complying with the applicable regulation).

The Court is not persuaded by this argument. To begin, the United States' brief does not even mention *Ketroser*, much less account for it. This is crucial since *Ketroser* re-affirms *Hixson*. Furthermore, the holdings of *Ketroser* and *Hixson* are clear, thus there is no need to "interpret" them at all. Accordingly, the Court holds that consistent with *Ketroser* and *Hixson*, a defendant is not liable under the FCA if the regulation is ambiguous and its statements would be true under a reasonable interpretation of the regulation.

2. Step three of the regulation is ambiguous because what constitutes "emergence" is unclear.

Applying *Ketroser* and *Hixson*, the Court must first consider whether step three of the Seven Steps regulation is ambiguous. The Court finds it is because what constitutes "personally participates in . . . emergence" is not clear. "Emergence" is not defined by CMS, a National

Coverage Determination, a binding Local Coverage Determination, or any national or state anesthesiology organization. Although there is a consensus within the anesthesiology community that emergence begins in the operating room with the cessation of the delivery of anesthetic agents, there is no agreement on when it *ends*. Relator's two experts and Palmetto GBA, the nationwide Medicare carrier for railroad retirees, view emergence as ending once the patient is turned over to the staff in the recovery room. But it is uncontroverted that anesthesiologists consider emergence to be a process that occurs over a period of time and may take an hour or more to complete, depending on the patient. The absence of a clear definition of when emergence ends means the regulation is ambiguous. *See Ketroser*, 729 F.3d at 831.

3. Defendant's interpretation of the regulation is reasonable, hence it is entitled to summary judgment.

Defendant defines "emergence" to include the patient's recovery in the recovery room. Although this may not be the most widely held or most reasonable definition of "emergence," it is a plausible definition. By extension, Defendant's view that the regulation is satisfied by seeing the patient in the recovery room is a reasonable interpretation.[11]

Of course, Defendant's interpretation is opportunistic because it has a financial motive to interpret the regulation this way. Under Relator's definition of "emergence," thousands of the procedures Defendant's anesthesiologists performed should have been billed at the lower Medical Supervision rate. But there is "no authoritative contrary interpretation" of the regulation here, and the Eighth Circuit has ruled that "a defendant does not act with the requisite deliberate ignorance or reckless disregard by 'taking advantage of a disputed legal question.'" *Hixson*, 613 F.3d at 1190-91 (quoting *Hagood*, 81 F.3d at 1478). While Relator has arguably put forth a

[11] The Court emphasizes it is making no ruling on whether seeing a patient in the recovery room is a reasonable interpretation of step three's requirement to personally participate in *the most demanding aspects* of emergence.

more reasonable interpretation of the regulation, this is not enough. Relator must carry its burden of showing "that there is no reasonable interpretation of the law that would make the allegedly false" claim valid. *Id*.

Defendant's reasonable interpretation of the regulation's ambiguity "belies the scienter necessary to establish a claim of fraud under the FCA." *Ketroser*, 729 F.3d at 832. At best, the evidence on the record suggests that Defendant may have negligently submitted 31 of 13,000 Medical Direction claims, which is not an FCA violation.[12] *See Allina Health*, 276 F.3d at 1053 ("[I]t is important to remember that the standard for liability is knowing, not negligent, presentation of a false claim."); *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002) (observing that negligence does not violate the FCA). Defendant is entitled to summary judgment on Counts I and II. Because the Court grants Defendant summary judgment on Counts I and II, it must deny Relator summary judgment on those same counts.

Conclusion

For the reasons discussed above, the Court GRANTS IN PART Defendant's motion to strike (Doc. 255); GRANTS Defendant's motion for summary judgment (Doc. 242); and DENIES Relator's motion for partial summary judgment (Doc. 236).

IT IS SO ORDERED.

Date: June 9, 2015

/s/ Greg Kays
GREG KAYS, CHIEF JUDGE
UNITED STATES DISTRICT COURT

[12] Starting with the 50 claims Relator submitted as representative examples of false claims and then subtracting the 19 claims where records held by MMC show that Defendant's anesthesiologist did, in fact, completely fill out the Anesthesia Services Record, yields 31 possibly false claims.